UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

Clinical Research or Clinical Practice

August 2020

Many research participants are also patients undergoing clinical care. Many study investigators are also clinicians providing clinical care. When is it important to clearly delineate between clinical research and clinical care? Always!

Contributing Authors: LCCC CPO, UNC OHRE, SOM CRSO

While clinical research is often integrated with clinical care, it is important to maintain clear lines between standard clinical practice and clinical research. Clinical practice focuses on providing benefit to the individual patient, while clinical research focuses on developing knowledge that is generalizable for future patients. In clinical practice, clinicians often offer variations in care plans to directly accommodate individual patients, but in clinical research, the study protocol dictates the specific care plan regimen. When patients receiving clinical care are also participants in clinical research studies, requirements and care considerations can become confusing for clinical care teams, the clinical research team and the patient/participant.

Consider the following from the perspective of the clinical care teams and clinical research teams:

Consideration	**Clinical Practice (Patient)**	**Clinical Research (Participant)**
Setting expectation of patient/participant	Expect to receive benefit from treatment	Understand they may or may not receive benefit from treatment
Defining treatment plans	Per practice's standard of care	Per study protocol
Making changes in treatment plans	Clinical judgement applied within standard of care guidelines	Follow requirements of the study protocol
Documentation of activities	Per clinical practice and facility requirements	Per study protocol, ICH GCP, and regulatory requirements
Facility used	May be altered based on patient preference and clinical practice	Per study protocol, availability of trained personnel, certified equipment

Note: While it is required to follow the study protocol for participants receiving treatment as part of a research study, clinician-investigators must demonstrate the same care for the well-being of research participants that they would for patients to whom they provide standard clinical care. If at any point the clinician-investigator believes that participating in the research study is no longer in the best interest of the patient/participant, he/she must inform the participant of the clinical recommendation. The study team must also ensure the participant remains aware of his/her right to withdraw from the research study at any time.

It is also important to ensure that research participants maintain understanding of the differences between clinical practice and clinical research, which can be particularly challenging when the treating clinician is also part of the study team. Whenever possible, it is recommended for a member of the study team who is not the treating clinician to obtain informed consent for research studies.

To promote clear understanding for patients/participants, consider the following during the informed consent process:

- Ensure clear understanding of clinical research in general: to gain generalizable knowledge to benefit people in the future
- Explicitly review what activities will be performed for or dictated by the study protocol
- Never promise therapeutic response from participating in a clinical research study
- Avoid using qualitative language like "luckily" or "great option;" provide neutral information to support the patient/participant in making an informed decision